



**Corbus Pharmaceuticals Holdings  
Third Quarter Earnings Conference Call  
November 10, 2020**

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**Operator:** Hello, and welcome to the Corbus Pharmaceuticals Third Quarter November 10, 2020 Earnings Conference Call. As a brief reminder, all participants are currently in a listen-only mode. If anyone requires operator assistance during the conference, please press star, zero on your telephone keypad. Following the presentation there will be a question-and-answer session. Do note that this conference is being recorded at the Company's request and will be made available on the Company's [website](#) following the end of the call.

I will now turn the conference over to your host, Ted Jenkins, Senior Director of Investor Relations and Corporate Communications. Please go ahead, sir.

**Ted Jenkins:** Thank you, operator, and good morning, everyone. Thank you for joining us today. At this time, I'd like to remind our listeners that remarks made during this call state management's intentions, hopes, beliefs, expectations, or projections of the future. These are forward-looking statements and involve risks and uncertainties. The forward-looking statements on this call are made pursuant to the Safe Harbor provisions of the federal securities laws.

These forward-looking statements are based on Corbus' current expectations, and actual results could differ materially. As a result, you should not place undue reliance on any forward-looking statements. Some of the factors that could cause actual results to differ materially from those contemplated by such forward-looking statements are discussed in the periodic reports Corbus files with the Securities and Exchange Commission. These documents are available in the [Investor](#) section of the Company's [website](#) and on the Securities and Exchange Commissions' [website](#). We encourage you to review these documents carefully.

Joining me on the call today are Dr. Yuval Cohen, our Chief Executive Officer; Dr. Barbara White, our Chief Medical Officer and Head of Research; Sean Moran, our Chief Financial Officer; and Craig Millian, our Chief Commercial Officer.

With that, it is now my pleasure to turn the call over to Yuval.

**Dr. Yuval Cohen:** Thank you, Ted. Thank you, everyone, for joining us this morning for our Third Quarter 2020 Earnings Conference Call. This past quarter has been by far the most challenging period for this Company since we started it in 2014, with disappointing top-line data in both the RESOLVE 1 Phase 3 study in systemic sclerosis and our Phase 2b cystic fibrosis study.

In each one of these studies, lenabasum did not meet its primary endpoint. This is a simple and rather brutal fact and is part and parcel of the inherent risks of drug development. What is now

relevant is, where do we go from here? Our plan to rebuild shareholder value revolves around three simple concepts.

The first one is we believe lenabasum is an active compound. These trials yielded valuable data that provides us with insight into potential clinical benefit associated with lenabasum in each one of these diseases. Barbara will walk you through the summaries of each of those shortly.

We believe that the data from these recent studies demonstrated that lenabasum had clinical activity in both systemic sclerosis and cystic fibrosis. They will allow us to map out a potential path forward that starts with us engaging with experts in these fields and other stakeholders. We continue to believe that there is real potential in these indications that could create value for Corbus.

The second concept is dermatomyositis represents a potentially significant value driver for next year. With 30,000 patients in the U.S. with clear, unmet need, dermatomyositis represents an attractive market opportunity that could create substantial shareholder value. A positive outcome in our Phase 3 DETERMINE study of lenabasum in dermatomyositis could increase the value of our Company.

We note recent changes in the dermatomyositis competitive landscape, with Phase 3 studies that are shorter than one year. Therefore, we plan to shorten the duration of the DETERMINE Phase 3 study from 1 year to just 28 weeks, accelerating top-line data readout to the spring of 2021.

We are leveraging our pipeline to create value beyond lenabasum. That is our third concept. Corbus is more than just lenabasum. We have a pipeline that is being developed both internally and with external assets. We believe our pipeline contains real value. We are prioritizing development of those preclinical assets that we believe can deliver a data value inflection point in 2021, either in the form of a potential partnership or a meaningful increase in our enterprise value.

We are evaluating options for expanding our pipeline further with external assets that offer synergy with our current pipeline and our expertise in taking programs from preclinical development all the way to complex Phase 3 studies. We look forward to our next Research and Development Day at which we will showcase our pipeline beyond lenabasum and the value we believe can be unlocked from it.

We are committed to rebuilding the value of Corbus for our shareholders. We have the expertise and the cash runway to do so because of the dramatic restructuring we undertook that significantly extended our cash runway into mid-2022 and with the shortening of the DM study potentially even further than that.

I will now turn the call over to Barbara. Barbara?

**Dr. Barbara White:** Thank you, Yuval. As you know, our Phase 3 study of lenabasum in systemic sclerosis and our Phase 2b study of lenabasum in cystic fibrosis did not meet their primary endpoints. In both studies, the safety profile of lenabasum remained unchanged and favorable, without evidence of immunosuppression. Post-hoc analysis showed what we believe to be evidence of clinical activity of lenabasum in both studies.

In the Phase 3 systemic sclerosis study, improvement in the placebo group was greater than expected and occurred mostly in subjects who started new immunosuppressant therapies within the last two years, compared to subjects who are on more established treatment regimens.

Subjects on mycophenolate, an immunosuppressant used in 51 percent of the subjects in this study, were especially associated with improvement in the placebo group. When post-hoc analyses were done in subjects treated with immunosuppressants for at least two years, improvement was seen in the lenabasum-treated groups, compared to the placebo groups, in Forced Vital Capacity, a measure of lung function, whether assessed as percent predicted or in milliliters.

Fewer subjects in this subset treated with established immunosuppressants had declines, and more had stability in Forced Vital Capacity, compared to subjects treated with placebo. Please refer to yesterday's press release for specific data.

Despite the improvement in subjects in the placebo group in the Phase 3 study of lenabasum in scleroderma, it remains clear that patients with systemic sclerosis still need new treatments of their overall disease and major organ-specific manifestations, especially new treatments with favorable safety profiles.

We are encouraged about the analysis that suggests that lenabasum may improve lung function in patients already on established immunosuppressant treatments, given the importance of controlling decline in lung function to the overall health and mortality of systemic sclerosis patients. Our next steps include additional analysis of the data to confirm these findings and then, if warranted, consideration of another Phase 3 study.

In our Phase 2b study of lenabasum for treatment of pulmonary exacerbations, or PEx, in people with cystic fibrosis, we found very low pulmonary exacerbation rates in 21 percent of total subjects, from five Eastern European countries, without regard to treatment assignment. Pulmonary exacerbation rates were about 85 percent lower in subjects in these countries than those in study participants from other countries. These low rates precluded observing a

meaningful difference in pulmonary exacerbation rates based on treatment assignment in subjects from these countries.

Post-hoc analyses were done that excluded subjects in the five countries with very low overall pulmonary exacerbation rates. In these analyses, we saw substantial differences in pulmonary exacerbation rates in the placebo group, depending upon baseline lung function and background treatment with CFTR modulating drugs.

When comparing subjects with similar baseline function and treatment with CFTR modulators, lenabasum treatment was associated with a range of numerical reductions in pulmonary exacerbations, up to a 62 percent maximum reduction, depending upon the comparison. These findings suggest activity of lenabasum in cystic fibrosis. Additional analyses are underway to extend these findings. The additional analysis will be done with input from the study's steering committee of experts in cystic fibrosis and the Cystic Fibrosis Foundation Therapeutics Development Network.

We are pleased to report that DETERMINE, the Phase 3 study of lenabasum in dermatomyositis, is progressing well, with more than 60 percent of subjects completing Week 28 already. Baseline characteristics of the subjects in the study were reported at the American College of Rheumatology Annual Meeting this year.

DETERMINE is the first study to enroll the full spectrum of patients with dermatomyositis, with 82 percent of subjects with the classic form of dermatomyositis with clinically apparent skin and muscle manifestations, and 18 percent of subjects with the amyopathic form of dermatomyositis with skin involvement but without clinically apparent muscle weakness. Stable use of background immunosuppressants was allowed in the DM study but differs from usage in the scleroderma Phase 3 study.

Mycophenolate was used at baseline in only 19 percent of the dermatomyositis subjects, compared to 51 percent of subjects in the scleroderma study. Use of intravenous immunoglobulin has been reported to improve dermatomyositis, especially during the first few months of treatment. In our dermatomyositis study, about 18 percent of subjects were receiving intravenous immunoglobulin at baseline, and only 5 percent of subjects had started that treatment recently, in the last year. We look forward to results of this important study in patients with dermatomyositis.

As Yuval mentioned, given recent industry developments, we plan to change the timing of the primary endpoint from 1 year to 28 weeks. This change would allow us to address earlier than we originally planned the question of whether lenabasum provides benefit in dermatomyositis, using a treatment duration consistent with other recent or ongoing Phase 3 studies in dermatomyositis.

Of note, recent findings in dermatomyositis skin biopsies further strengthens the case for lenabasum as a potential treatment for DM. As presented in an abstract at the ACR Annual Meeting, expression of CB2, cannabinoid receptor type 2, was increased on immune cells in lesional skin from dermatomyositis subjects in the lenabasum Phase 2 study. Treatment with lenabasum was associated with a reduction in immune cell infiltrates, CB2 expression, and inflammatory cytokine production in lesional skin from these people with dermatomyositis.

The NIH-sponsored, 100-patient Phase 2 study of lenabasum in systemic lupus erythematosus has enrolled 93 of 100 planned subjects to date. We remain optimistic that enrollment may be complete by either year end or early next year, with top-line data in the first half of 2021.

We have promising preclinical programs that we view as a key component in rebuilding shareholder value. We are especially encouraged by preclinical data we've generated with a novel family of CB2 agonists that inhibit tumor cell growth *in vitro* and in a xenograft model of human cancer.

This potential anti-tumor activity of several of our own CB2 agonists is supported by a robust literature testing other CB2 agonists in animal models. We are preparing to submit this data to an upcoming medical conference, and we'll be increasing internal resources devoted to this program.

Regarding our CB1 inverse agonist program, we have recently identified several compounds with more promising physical, chemical, and pharmacokinetic properties than CRB-4001. We are shifting our focus to prioritize development of these compounds and are not continuing to develop CRB-4001. We look forward to disclosing more details about these compounds at a future R&D Day.

With that, I will turn the call back to Yuval.

**Dr. Yuval Cohen:** Thank you, Barbara. I will now provide an update regarding our financial position. I've mentioned previously, in October we announced a very dramatic restructuring of our operations, designed to reduce costs and reallocate resources towards our lenabasum clinical development program in dermatomyositis as well as our early-stage pipeline. The restructuring, which included layoffs and other cost reductions, was designed to extend our cash runway of \$82 million to mid-2022.

Lastly, a valued member of our senior leadership team, our Chief Operating Officer, Bob Discordia, has resigned from the Company to pursue other interests. Bob played an important role and made many contributions during a critical period for the Company, and his presence

will be genuinely missed. On behalf of the senior leadership team, I would like to personally thank Bob for his leadership, service, and commitment. We wish him well.

In closing, we continue to believe the endocannabinoid system is a key target for the development of therapeutics for the treatment of debilitating diseases. With these unique clinical databases now in hand, we will continue to collaborate with both systemic sclerosis and cystic fibrosis experts and explore the road map to potential follow-on confirmatory studies for both programs.

We are excited for the completion of our Phase 3 clinical trial in DM next year with an anticipated top-line data readout less than one year away and potentially sooner than initially planned. We also look forward to data from our SLE program next year. We are actively prioritizing our pipeline to focus on those programs that we can deliver at the earliest data inflection point and look forward to providing you with an update at an upcoming Research and Development Day.

With that, I want to thank you all for your time and attention today. I now turn the call back to the operator, and we will open the call to questions from the audience.

**Operator:** Thank you. We will now be conducting a question-and-answer session. If you would like to ask a question, please press star, one on your telephone keypad. A confirmation tone will indicate your line is in a question queue. You may press star, two if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star key. One moment, while we poll for our first question.

Our first question comes from Brian Abrahams with RBC Capital Markets. Please proceed.

**Brian Abrahams:** Hey, guys. Thank you for taking my questions. I guess my first question is on the dermatomyositis study. I'd love to hear a little bit more about the rationale behind shortening the study. Obviously, you can get a quicker readout. But, I'm just sort of wondering what this means for the overall conduct and powering of the study, if you're expecting most of the effects will be observed within those first six months, and if there are any additional FDA or regulatory sign-offs that you need in order to amend the protocol and have it potentially still enable an adequate safety database to enable registration?

**Dr. Barbara White:** Brian, this is Barbara. Thank you very much for that question. In response, a number of things have changed since we first planned the study. And we were the first large Phase 3 study in dermatomyositis, and there have been a number of studies since that point. We had originally planned for a study duration of 52 weeks, but we note that Octagam just

reported Phase 3 results in a study of a duration of 16 weeks, which is far less than the 52-week study we had planned.

Also, when we look at study durations for other Phase 3 studies in dermatomyositis, all the ones that we can see are less than 52 weeks and range from 16 weeks, 17 weeks to 24 weeks. So, in fact, our dermatomyositis study is the outlier in terms of treatment duration and competitively, I think the data would be compared from comparable time points. So, I think it's reasonable to determine what our efficacy is at these earlier time points.

When we look at blinded data from our study, and it is blinded, we know already that we've had good progress in the study and that more than 60 percent of the patients are through Week 28 and that a number of them have already completed the study, so that we can get a reasonable idea of what the overall rate of response is in the primary outcome, which is the total improvement score.

And when we do this, with the data to date, about 85 percent of the improvement is already apparent in these analyses of blinded data, about 85 percent of improvement is already apparent by Week 28. So, while improvement continues beyond that, the majority of improvement occurs in the first six months or so.

So, I don't think we'll be losing a lot of signal; a lot of value, by shortening the study. The trade-off for loss of efficacy I don't think will be great. So, I think that's important. It's what other studies are doing, trade-off is not great. It will provide us with a major inflection point sooner than we would otherwise--six months. So, the time point to get the last patient out at 28 weeks will be sometime at the juncture of the first and second quarter next year.

And if the study is positive, we think that this will provide meaningful value for the Company. We don't think that it necessarily precludes the opportunity to take the data on for approval. We certainly will need to have a protocol amendment and revise the statistical analysis plan. These things can be done. But as I repeat, this study design with an outcome shorter than 52 weeks would be quite consistent with what others are doing in their Phase 3 studies.

**Brian Abrahams:** Got it. That's really helpful color, Barbara. And then just maybe one more question from me--just curious if you could expand a little bit more about some of the limitations that you observed with 4001 on the formulation side, on the blood-brain barrier penetration side, and, I guess, what the--maybe some of the characteristics of the next generation CB1 inverse agonists, when we could learn more about those moving forward into the clinic?

**Dr. Barbara White:** Sure. Thank you, Brian, again for the question. We actually had both of those. We observed both of those problems with 4001. We have a fabulous CMC team and they



were and have been able to make formulations of 4001 that were adequate for us to begin our clinical testing. Nonetheless, it's a fairly insoluble, difficult-to-formulate compound.

In addition, we extended and expanded upon the initial toxicology and pharmacokinetic studies that had been done and had previously been adequate to enable Phase 1 testing. But for safety purposes, we decided to expand these studies. And when we did this, we found levels of 4001 in primate brain that we felt did not support further development of 4001.

The other compounds that we are pursuing have more favorable physical chemical properties in terms of likely solubility and ability to formulate. And also in the studies that we've done to-date, they don't show some of the early signals of concern about 4001 and its accumulation in brain.

Does that help, Brian?

**Brian Abrahams:** Very helpful. Thanks again, guys.

**Operator:** Our next question comes from Dr. Maury Raycroft with Jefferies. Please proceed.

**Kenny Chan:** Hi, this is Kenny Chan on for Maury Raycroft. I have a question on the systemic sclerosis trial. How do you see the greater-than-two-year IST mark from the recent post-hoc press release incorporated into the FDA label? Has there been precedent for approvals based on years of background therapy failure, or would you run additional trials, either in-house or with a partner?

**Dr. Barbara White:** Hi, Kenny. Thanks for the question. To be clear, we do not think that the current Phase 3 study that was just completed is adequate to support regulatory approval, so we've taken that off the books. We didn't meet the primary, and therefore we didn't meet the secondary. And we just don't think that that's a path forward to approval.

At the same time, we think the data are very informative, not only to us but to the clinical community. And they provide a very rich database from which we can further discern how to design an additional Phase 3 study that then could be used for approval. So, again, the one that was just finished is not adequate for approval. We are in the process of determining a path forward. And if we do move forward, that would, by necessity, involve another Phase 3 study.

**Kenny Chan:** Thanks. And one more question on CF. You previously mentioned that you will talk to the CF community regarding approvability and potential trials. Have you any feedback?

**Dr. Barbara White:** Yes, we've had some conversations, and we will engage in more. At this point, we're still a little bit early to think about that. But at the same time, I do want to point

out that we failed to meet our primary endpoint, and usually, generally, that precludes that trial being used to support--if it could support approval--but it precludes that trial being used as the basis for approval.

**Kenny Chan:** Gotchya. And maybe just one last question. For DM, was the trial shortened based on competitors, or did you feel there was efficacy read-through from CF or SSc that contributed to that shortened decision?

**Dr. Barbara White:** I think it was more the former, that we continue to assess the evolving status of trials in dermatomyositis. We've seen that they're all at least half as short as ours is and we think that that's the time point that, should lenabasum be effective, physicians would use to judge efficacy in comparison to other compounds that may be available and will be at an earlier time point. So, we felt it was very reasonable to see what the lenabasum data looked like. That enables us to do that.

**Kenny Chan:** Gotchya. Thanks.

**Operator:** Once again, ladies and gentlemen, to ask a question, please press star, one on your telephone keypad. Our next question comes from Leland Gershell with Oppenheimer. Please proceed.

**Leland Gershell:** Good morning. Thanks for taking my questions. First, a question on systemic sclerosis. With the identification of the pulmonary function improvement potential that you've seen with lenabasum from the RESOLVE data, it sounds like you're contemplating going forward potentially with a focus on that. Just wondering, Barbara or Yuval, if you can comment on when we might hear clarity on the decision process to move forward in SSc with a focus on FVC and what further you may need to go into that consideration as you make that decision? And then, I have a follow-up. Thanks.

**Dr. Barbara White:** So, I'll start and then pass it to Yuval. And thank you, Leland, again, for your question and your interest. We will do some additional data analysis. As you can appreciate, these are post-hoc analyses, and post-hoc analyses are fraught with that, that they are after the fact, although we did certainly call out the need to look at Forced Vital Capacity ahead of time. That was one of our secondary endpoints. We just hadn't known the impact of background immunosuppressants ahead of time.

So, we will continue to analyze the data to convince ourselves and experts on this improvement that we're seeing in FVC is indeed as robust as we think it is in these analyses to-date. And when we've done that, and that shouldn't take too much longer, then a next step is to design an additional study and to gain agreement from regulatory authorities that such a Phase 3 design would be appropriate to support approval.

We note that Forced Vital Capacity has already been used as a primary efficacy endpoint in a successful Phase 3 study. OFEV has been approved for treatment of lung function, of lung involvement in patients with systemic sclerosis recently. So, the regulatory path forward, focusing on lung function, to us seems pretty clear.

**Leland Gershell:** Thank you. Yuval, do you have any additional comment?

**Dr. Yuval Cohen:** Not especially. It's intriguing. We want to make sure we have a full handle on it. I think that another thing that will be important is, really talk to a whole bunch of people out there in the scleroderma landscape, see what they think, if any of them is--again, their feedback, their interest and then obviously, in parallel, start a regulatory path. My guess is it's certainly a next-year event, and we'll be busy working on it from now and into Q1.

**Leland Gershell:** Thanks. That's helpful. And then with regard to the 4001 program, just curious if in the earlier stage compound that looked to be more attractive versus that one, given that finding, wondering if you plan to announce multiple development candidates that could be evaluated in parallel in the clinic, or it will be the case that you will settle on one that you'll take forward based on the preclinical profiles, just in terms of hedging your bets on that opportunity?

**Dr. Barbara White:** Leland, thank you. That's an interesting thought. Right now, our plan would be to move the one that appears better forward into clinical development. Certainly, the other two or several would be an option, but to move one would probably be more conservative for our resources. And we would hope to have enough data preclinically to pick the best of what now look to be several promising compounds.

**Leland Gershell:** Alright, great. Thanks very much for taking the question.

**Operator:** Thank you. We have reached the end of our question-and-answer session. Ladies and gentlemen, that concludes today's teleconference and webcast. You may disconnect your lines at this time and have a wonderful day. We thank you for your participation.